1.4 product information

1.4.1 Prescribing information (Summary of product characteristics)

1. Name of the medicinal product

Zinc Sulfate Dispersible Tablets

2. Qualitative and quantitative composition

Each tablet contains: Zinc Sulfate Monohydrate 54.890mg equivalent to 20mg elemental zinc and excipients provided in section 6.1

3.Pharmaceutical form

Tablets for oral administration.

Dispersible tablets

White to off white, circular FFBE tablets scored on one side and plain on reverse, packed in blisters of 1 x 10's and

10 x 10's and contained in a unit box with literature insert.

4. Clinical particulars

4.1 Therapeutic indications.

Zinc Sulfate is indicated as a dietary supplement and also in the treatment of a large number of conditions that may be related to zinc deficiency. Chronic diarrhoea can be a sign of zinc deficiency. Diarrhoea can also lead to excessive zinc losses and zinc deficiency when dietary zinc is inadequate. Zinc supplements have been shown to reduce incidence, intensity or the duration of acute diarrhoea in children. Supplementation with zinc also has beneficial effects on persistent diarrhoea.

4.2 Posology and method of administration

Oral zinc supplementation at a dose of 10 to 20mg daily for 14 days is efficacious in significantly reducing the severity and duration of diarrhoea. Infants aged 6 months and below should be given half a tablet daily. Older children of up to 5 years old should be given one tablet daily. Zinc sulfate tablets are dispersible and should be dissolved first prior to administration in a 5ml spoonful of milk (breast milk is better) for infants who are breastfeeding or clean drinking water or other suitable drink for older children.

It is strongly recommended that administration of zinc sulfate tablets be carried out concurrently with therapy using oral rehydration salts (ORS).

It is preferable that treatment with zinc sulfate be given with meals or milk to avoid any possible gastrointestinal disturbance.

Method of administration

Oral administration

4.3 Contraindications

Not Applicable.

4.4 Special warnings and precautions for use.

Drugs which may inhibit zinc absorption, such as penicillamine, sodium valproate and ethambutol, should not be co-administered with Zinc sulfate Tablets, unless the risks of discontinuation of the drug are judged to outweigh the benefit of zinc in treatment of the child's diarrhoea. Excipients Zinc sulfate Tablets contain aspartame, a source of phenylalanine. This should be considered when prescribing the product to patients with phenylketonuria.

4.5 Interaction with other medicinal products and other forms of interaction

Zinc supplements reduce the absorption of copper, fluoroquinolones, iron, penicillamine, and tetracyclines.

4.6 Pregnancy and lactation

Pregnancy: The safety of Zinc sulfate tablets in pregnancy has not been established.

Lactation: Zinc crosses the placenta and is present in breast milk. The safety of Zinc sulfate tablets in lactation has not been established.

4.7 Effects on ability to drive and use machines

Not Applicable.

1.8 Undesirable effect

The most frequent adverse effects of zinc salts when given orally are gastrointestinal and include abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation, and gastritis particularly if taken on an empty stomach. Prolonged use of high doses of zinc supplements leads to copper deficiency resulting in sideroblastic anaemia and neutropenia.

4.9 Overdose and treatment

In acute over-dosage, zinc salts form corrosive zinc chloride in the stomach. Treatment is by administration of milk or alkali carbonates and activated charcoal.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other mineral supplements, ATC code: A12CB01
Zinc sulfate is a water-soluble salt with a solubility of 1gm in 0.6ml of water. Zinc is an essential element with a recommended adult daily allowance of between 7.5mg and 13mg depending on gender.
Zinc is a constituent of many enzyme systems and is present in all body tissues. Deficiency in Zinc leads to growth retardation and defects of rapidly-dividing tissues such as the skin, the immune system and the intestinal mucosa.

5.2 Pharmacokinetic properties

Absorption and fate

The absorption of Zinc from the gastrointestinal tract is incomplete and is reduced in the presence of some dietary phytates. The ionic nature of the salt confers to it high hydrophilicity therefore reducing 1ts absorption rate through the hydrophobic mucosa of the gastrointestinal tract. The bioavailability of dietary zone vanes widely between different sources but is about 20 to 30 percent. The absorbed zinc is distributed throughout the body with the highest concentrations found in muscles bones skin, eyes and prostatic fluids. Zinc is excreted primarily in feaces but small amounts are excreted in urine and through perspiration. Absorption of zinc may be reduced by iron supplements, penicillamine, phosphorous-containing preparations and tetracyclines.

5.3 Preclinical data safety

Non-clinical data have not revealed significant hazards for humans, based on standard studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and reproductive toxicity. Effects in non-clinical studies were observed only at exposures sufficiently in excess of the maximum human exposure to be of little clinical relevance.

6. Pharmaceutical particulars

6.1 List of excipients

Microcrystalline Cellulose pH 102
Croscarmellose Sodium
Crospovidone
Aspartame
Vanilla Flavour
Magnesium Stearate
Aerosil 200 Pharma.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months from the date of manufacture.

6.4 Special precautions for storage

Store in a dry place below 30°C.
Protect form light.
Keep all medicines out of reach of children.

6.5 Nature and contents of container

Blister Packs: Blisters of 1x10's & 10 x 10's tablets in PVC/ Aluminium Foil contained in a unit box along with literature insert.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses Marketing Authorization Holder:

Company Name: LABORATORY & ALLIED LTD
Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road,
P.O. Box 42875 GPO 00100, Nairobi,
Country: Kenya
Telephone: +254 20 8040306
Telefax: +254 20 8040309
E-Mail: info@laballied.com.

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9. Date of first Registration/ Renewal of the Registration:

Marketing Authorization Number: H2015/CTD375/579.
First registration date: 13th/11/2015.
Renewal: Retained annually.

10. Date of revision of the text:

February 2024.